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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/580,281	05/30/2000	Yuhpyng L. Chen	PC8605C	1660
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EXAMINER

JONES, DWAYNE C

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Applicant(s)

09/580,281

CHEN, YUHPYNG L.

Examiner

Dwayne C Jones

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on the response of 04 APR 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 15-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 15-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Status of Claims***

1. Claims 1-28 are pending.
2. Claims 1-14 are elected and rejected.
3. Claims 16-28 are non-elected and withdrawn from further consideration.

### ***Election/Restrictions***

4. Applicant's election with traverse of Group I, corresponding to claims 1-14, which are directed to compounds and pharmaceutical compositions of said compounds, in Paper No. 7 is acknowledged. In addition, the compound of [2,5-dimethyl-6-(tetrahydrofuran-3-yloxy)-pyrimidin-4-yl]-(2,4,6-trimethylphenyl)-amine was elected as a species as well as the disorder of depression, however these compounds were found in the prior art. The traversal is on the ground(s) that Groups I and II should be examined together. This is not found persuasive because the plethora of ailments and conditions of Group II can be treated with compounds other than those disclosed in Group I, such as with Prozac.

5. The requirement is still deemed proper and is therefore made FINAL.

### ***Priority***

6. If applicant desires priority under 35 U.S.C. 120 based upon a previously filed copending application, specific reference to the earlier filed application must be made in the instant application. This should appear as the first sentence of the specification

Art Unit: 1614

following the title, preferably as a separate paragraph. The status of nonprovisional parent application(s) (whether patented or abandoned) should also be included. If a parent application has become a patent, the expression "now Patent No. \_\_\_\_\_" should follow the filing date of the parent application. If a parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

If the application is a utility or plant application filed on or after November 29, 2000, any claim for priority must be made during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2) and (a)(5). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) a surcharge under 37 CFR 1.17(t), and (2) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Commissioner may require additional information where there is a question whether the delay was unintentional. The petition should be directed to the Office of Petitions, Box DAC, Assistant Commissioner for Patents, Washington, DC 20231.

***Oath/Declaration***

7. A new oath or declaration is required because the reference to Serial No. 09/254,387 in the declaration has an improper filing date of June 6, 1995 instead of March 4, 1999. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

***Claim Rejections - 35 USC § 112***

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons support this rejection. The compound of formula I has the variable of A to represent only one moiety, which is the nitrogen atom. When the variable of "Z" is defined as, "N(C<sub>1</sub>-C<sub>2</sub> alkyl), NC(O)CF<sub>3</sub> or C(R<sub>13</sub>R<sub>14</sub>)" each of these three groups have incomplete valencies. When the variables of R<sub>1</sub>, R<sub>2</sub> are C<sub>1</sub>-C<sub>6</sub> alkyl, C<sub>1</sub>-C<sub>6</sub> alkylene, C<sub>5</sub>-C<sub>8</sub> cycloalkyl, C<sub>5</sub>-C<sub>8</sub> cycloalkylene and C<sub>5</sub>-C<sub>8</sub> heterocycloalkyl moieties, it is further stated that "R<sub>1</sub> may optionally independently contain from one to three double or triple bonds." In addition, when the variables of R<sub>4</sub>

Art Unit: 1614

and  $R_5$  are alkyl and alkylene groups, it is stated that these groups "may optionally independently contain one or two double or triple bonds." Also, when the variable of  $R_6$ ,  $R_{16}$ ,  $R_{17}$  have a  $C_1$ - $C_4$  alkyl substituent which "may optionally contain one double or triple bond." Moreover, with variables  $R_{24}$  and  $R_{25}$  the  $C_4$ - $C_8$  heterocycloalkyl groups can be substituted with  $C_1$ - $C_4$  alkyl which can further be "optionally contain one or two double or triple bonds". However, the fact that alkyl and cycloalkyl groups can only possess single bonds, not double and triple bonds, presents ambiguity to the claim.

The variable of  $R_4$  on line 1 of page 136 is defined as the substituent of " $CH_2OF_3$ " which is causes indefiniteness because the valency of fluorine is exceeded. In addition, the variable of  $R_4$  on line 2 of page 136 is defined as  $C=NOR_{24}$ . However, the valency for the carbon atom of  $C=NOR_{24}$  is incomplete and renders the claim vague and indefinite.

The variable of  $R_5$  on line 15 on page 136 for the group " $CO(NOR_{22})R_{23}$ " has incomplete valency. The variable of  $R_5$  on line 19 of page 136 is defined as the variable of "nitro halo". It appears that a comma is missing between these two substituents. Also, the variable of  $R_5$  is redefined as  $R^5$ , which is inconsistent with the variable listed in formula II. All of these issues are unclear and thus render the claims vague and indefinite.

10. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claims 1-14 recite the limitation for the variable of  $R_2$  that "the  $C_5$ - $C_8$  cycloalkyl,  $C_5$ - $C_8$  cycloalkylene, and  $C_5$ - $C_8$  heterocycloalkyl" in lines 18-19 on page 135. There is insufficient antecedent basis for this limitation in the claim.

Art Unit: 1614

12. Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

13. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 1 recites the broad recitation "C<sub>1</sub>-C<sub>4</sub> haloalkyl", and the claim also recites "especially CF<sub>3</sub>, CHF<sub>2</sub>, CF<sub>2</sub>CF<sub>3</sub> or CH<sub>2</sub>CF<sub>3</sub>" which is the narrower statement of the range/limitation.

14. Claim 13 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

15. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since

Art Unit: 1614

the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 13 recites the broad recitation "inflammatory disorders", "phobias", "pain perception", "mood disorders", "depression", "neurodegenerative diseases", "eating disorders", "addictions", "neuronal damage", "cerebral ischemia", "immune dysfunctions", "stress induced immune dysfunctions" and the claim also recites "such as rheumatoid arthritis", "including social phobia", "such as fibromyalgia", "such as depression", "including major depression", "such as Alzheimer's disease", "such as anorexia", "including dependencies", "including cerebral ischemia", "for example cerebral hippocampal ischemia", "including stress induced immune dysfunctions", "including porcine stress syndrome", respectively which are the narrower statements of the ranges/limitations.

16. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.



Art Unit: 1614

17. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 14 recites the broad recitation "inflammatory disorders", "pain perception", "mood disorders", "depression", "neurodegenerative diseases", "eating disorders", "immune dysfunctions", "in a mammal" and the claim also recites "such as rheumatoid arthritis", "such as fibromyalgia", "such as depression", "including major depression", "such as Alzheimer's disease", "such as anorexia", "including stress induced immune dysfunctions", "including a human", respectively, which are the narrower statements of the ranges/limitations.

Art Unit: 1614

***Claim Rejections - 35 USC § 102***

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

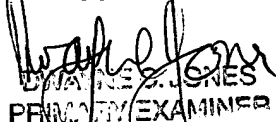
19. Claims 1-14 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Chen of WO 95/33750 possessing a publication date of December 14, 1995. Chen teaches of the corticotropin-releasing factor antagonist compounds and pharmaceuticals of formula (I), (see abstract and claims 1-14).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-

1235.

  
DIANNE S. JONES  
PRIMARY EXAMINER

Tech. Ctr. 1614  
June 16 2002